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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,988	11/13/2003	Leslie W. Organ	50162-042	6765
7590 McDermott, Will & Emery 600 13th Street, N.W. Washington, DC 20005-3096		11/27/2007	EXAMINER NGUYEN, HUONG Q	
			ART UNIT 3736	PAPER NUMBER
			MAIL DATE 11/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/705,988

Applicant(s)

ORGAN ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 59-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 59-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 September 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 9/12/2007. Claims 59, 65 are amended, overcoming the previous claim objections. The amendment to the drawings is acknowledged, overcoming the previous drawing objections. The amendment to the specification to include the priority date is also acknowledged. The previous §112 1st rejection is also withdrawn in light of Applicant's persuasive remarks. **Claims 59-72** remain pending.

Specification

2. The amendment filed 9/12/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "in some embodiments, gap 46a, shown in Figure 6, is utilized to prevent a direct conductive path immediately between the two ground connections 60. The consequence of gap 46a is that the conductive path extends from the ground connection 60 through each of the electrode tabs 52 and connector tabs 46 before reading the second ground connection 60." This specific explanation of said gap is not believed to have been disclosed in such detail prior to said amendment. If this is not true, Applicant is requested to point of specific portions of the specification disclosing such.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. **Claims 62-64** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding **Claim 62**, it is not understood what is meant by a gap in the spacing of the unlinked conducting surfaces of the electrode array and how it may be positioned with respect to the adjacent selected conducting surfaces of the conductor so that the continuous conductive path does not extend directly therebetween. How does this gap function?

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 59-68** are rejected under 35 U.S.C. 103(a) as being unpatentable over Faupel et al (US Pat No. 5660177) in view of Church et al (US Pat No. 5277197).

7. In regards to **Claim 65**, Faupel et al disclose a method of forming an operable electrical contact between a plurality of spaced unlinked conducting surfaces 182 of an electrode array 176 best seen in Figure 11 and a plurality of spaced unlinked conducting surfaces 188 of a connector 186 best seen in Figure 11, the method comprising: a) placing the electrode array and connector in electrical contact with respect to one another by overlapping the spaced unlinked conductive surfaces of the electrode array with the spaced unlinked conductive surfaces of the connector to

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form a continuous conductive path between two selected conducting surfaces (Col.18: 35-54). It is noted that overlapping is defined by www.dictionary.com as simply as “extend over and cover a part of,” which occurs when connector 186 is placed in electrical contact with the electrode array 176.

8. However, Faupel et al do not disclose measuring a test signal over the conductive path between the two selected conducting surfaces to see if an operable electrical contact has been established. Church et al teach measuring a test signal over a conductive path between two selected conducting surfaces to see if an operable electrical contact has been established (Col.9: 16-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Faupel et al to include the step of measuring a test signal over the conductive path between the two selected conducting surfaces to see if an operable electrical contact has been established, as taught by Church et al, for proper confirmation of electrical contact.

9. In regards to **Claim 66**, Faupel et al disclose the conductive path is a ground conductive path.

10. In regards to **Claim 67**, Church et al disclose electrical resistance is measured and compared to a pre-established value for an operable electrical contact (Col.9: 16-24).

11. In regards to **Claim 68**, Faupel et al in combination with Church et al disclose placing the electrode array 176 and connector 186 in electrical contact with respect to one another places respective terminals 128 for electrodes 106 of the electrode array into electrical contact with respective conductive surfaces 188 of the connector as shown in Figure 11 of Faupel et al and the

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test establishes whether proper electrical contact between the respective terminals and conductive surfaces has been established.

12. **Claims 59-64** are rejected under 35 U.S.C. 103(a) as being unpatentable over Faupel et al in view of Church et al, further in view of House, Sr. (US Pat No. 4660562).

13. In regards to **Claim 59**, Faupel et al in combination with Church et al disclose the invention above but do not disclose the number of connections in the conductive path of the electrode array is minimized to two. House, Sr. discloses an analogous device wherein the number of connection in a conductive path is minimized to two for effective use (Col.1: 55-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Faupel et al and Church et al such that the number of connections in the conductive path of the electrode array is minimized to two as taught by House, Sr to provide the most effective use of diagnosing the presence of a disease state in a living organism.

14. In regards to **Claim 60**, Faupel et al in combination with Church et al disclose the invention above including the spaced unlinked conducting surfaces 182 on the electrode array 176 are spaced generally around an opening provided by the array, best seen in Figure 11, but do not disclose the spaced unlinked conducting surfaces 188 on the connector 186 are spaced around a similar opening provided by the connector. House, Sr discloses an analogous device wherein conducting surfaces (30,32,34,36) on an electrode array are spaced generally around an

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opening (20, 68, 66) provided by the array best seen in Figure 1 and 5, and conducting surfaces (78,80,82,84) on a connector are spaced around a similar opening provided by the connector, best seen in Figure 6, to allow the electrode array and connector to fit together effectively.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the connector of Faupel et al as modified by Church et al such that the spaced unlinked conducting surfaces on the connector are spaced around an opening provided by the connector similar to the opening of the electrode array as taught by House, Sr to enable the electrode array and the connector to fit together effectively.

15. In regards to **Claim 61**, Faupel et al disclose the two selected conducting surfaces of the connector 186 are adjacent to one another, best seen in Figure 11.

16. In regards to **Claim 62**, Faupel et al in combination with Church et al and House, Sr disclose a gap is provided in the spacing of the unlinked conducting surfaces 182 of the electrode array 176 best seen in Figures 11 so that when the electrode array and connector 186 are placed in overlapping relation the gap is positioned with respect to the adjacent selected conducting surfaces of the connector so that the continuous conductive path does not extend directly therebetween.

17. In regards to **Claim 63**, Faupel et al disclose an alignment means 184 is provided to ensure that the electrode array 176 and connector 186 overlies to form a continuous conductive path between the two selected conducting surfaces, best seen in Figure 11.

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18. In regards to **Claim 64**, Faupel et al disclose the conductive path is a ground conductive path.

19. **Claims 69-72** are rejected under 35 U.S.C. 103(a) as being unpatentable over Faupel et al in view of Church et al, further in view of Corasanti (US Pat No. 3841312).

20. In regards to **Claim 69**, Faupel et al in combination with Church et al disclose the step of diagnosing the presence of a disease state in a living organism from a plurality of electrode array elements 176, wherein each electrode array element comprises a body 194 having at least one arm 192 extending from the body with at least one electrode 106 provided on the arm, best seen in Figure 11. However, Faupel et al and Church et al do not disclose the step of diagnosing comprising: a) overlying the plurality of electrode array elements at the respective bodies thereof to form a main body of the electrode array with the arms of the respective electrode array elements extending from the main body in spaced relation; and b) clamping the plurality of electrode array elements together.

21. Corasanti discloses a method overlying a plurality of electrode elements at the respective bodies thereof to form a main body and clamping the plurality of electrode elements together, best seen in Figures 6-10, to provide an effective electrode arrangement that promotes better contact between the surface of the living organism and the electrode (Col.4: 15-55).

22. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Faupel et al and Church et al to include the steps of overlying a plurality of electrode array elements at the respective bodies thereof to form a main

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body of the electrode array and clamping the plurality of electrode elements together as taught by Corasanti to provide a superior electrode arrangement designed to maintain close contact between the surface of the living organism and the electrode array.

23. In regards to **Claim 70**, Faupel et al disclose alignment means is provided to ensure that the arms (192) of the respective electrode array elements (176) extend around the main body (194) of the electrode array in spaced relation, best seen in Figure 11.

24. In regards to **Claim 71**, Corasanti discloses a retaining member (42) is used in clamping the plurality of electrode array elements together, best seen in Figures 3-9, and the retaining member comprises a stiffening member adapted to flatten part of the tissue of the living organism being diagnosed (Col.3: 66-68, Col.4: 1-5).

25. In regards to **Claim 72**, Corasanti discloses the stiffening member (42) is in the form of a ring, best seen in Figure 4.

Response to Arguments

26. Applicant's arguments with respect to claims 59-72 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN

jen

Max Hindenburg